



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 27 1999 9 42 1 '99 JUN -2 P1:21

Mr. Robert P. Carraher
Pharmaton Natural Health Products
900 Ridgebury Road
P.O. Box 368
Ridgefield, Connecticut 06877

Dear Mr. Carraher:

This is in response to your letter of April 28, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Pharmaton Natural Health Products is making the following claims, among others, for the product **Prostatonin**:

"Clinically proven by doctors to promote normal urinary patterns"
"Clinically proven to help manage frequent urination at night"
"...effectively helps you better manage sleep disruptions due to frequent urination and the urgency experienced between bathroom visits"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease, namely, benign prostate hypertrophy. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 272

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Dorsey)

r/d:HFS-456:RMoore:5/4/99

Init:GCF-1:ABarnett:5/25/99

f/t:HFS-456:rjm:5/26/99:docname:64910.adv:disc37



Robert P. Carraher
EXECUTIVE DIRECTOR, MARKETING

April 28, 1999

VIA HAND DELIVERY

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Re: PROSTATONIN Dietary Supplement for Urinary & Prostate Health

To Whom It May Concern:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pharmaton Natural Health Products (Pharmaton), Division of Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, Ridgefield, Connecticut 06877, wishes to notify the Food and Drug Administration that within the past 30 days the Company has begun marketing a dietary supplement with a label which bears statements of nutritional support. Pharmaton is the distributor of the product.

The dietary supplement for which the statements are made is PROSTATONIN SOFTGEL® Capsules, which consist of the ingredients standardized pygeum africanum extract PY 102 (bark), 25 mg, and standardized urtica dioica extract UR 102 (root), 300 mg, per capsule.

The statements of nutritional support for this product read as follows:

Dietary supplement for urinary & prostate health.

Clinically proven by doctors to promote normal urinary patterns.

Clinically proven to help manage frequent urination at night.

Clinically proven to support prostate health.

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As men age, their testosterone hormone levels can start to decrease which may affect prostate function. PROSTATONIN helps men maintain a normal hormonal balance which promotes normal urinary flow and prostate health.

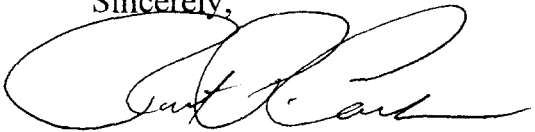
When taken as directed, PROSTATONIN's dual-herbal formula safely and effectively helps you better manage sleep disruptions due to frequent urination and the urgency experienced between bathroom visits.

A copy of the package for the product is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease. (The information is printed in bold in a box.)

The Company certifies that it possesses adequate substantiation for these statements of nutritional support which renders the statements truthful and non-misleading, and thus permissible under the DSHEA, and that the information contained in this notice is complete and accurate.

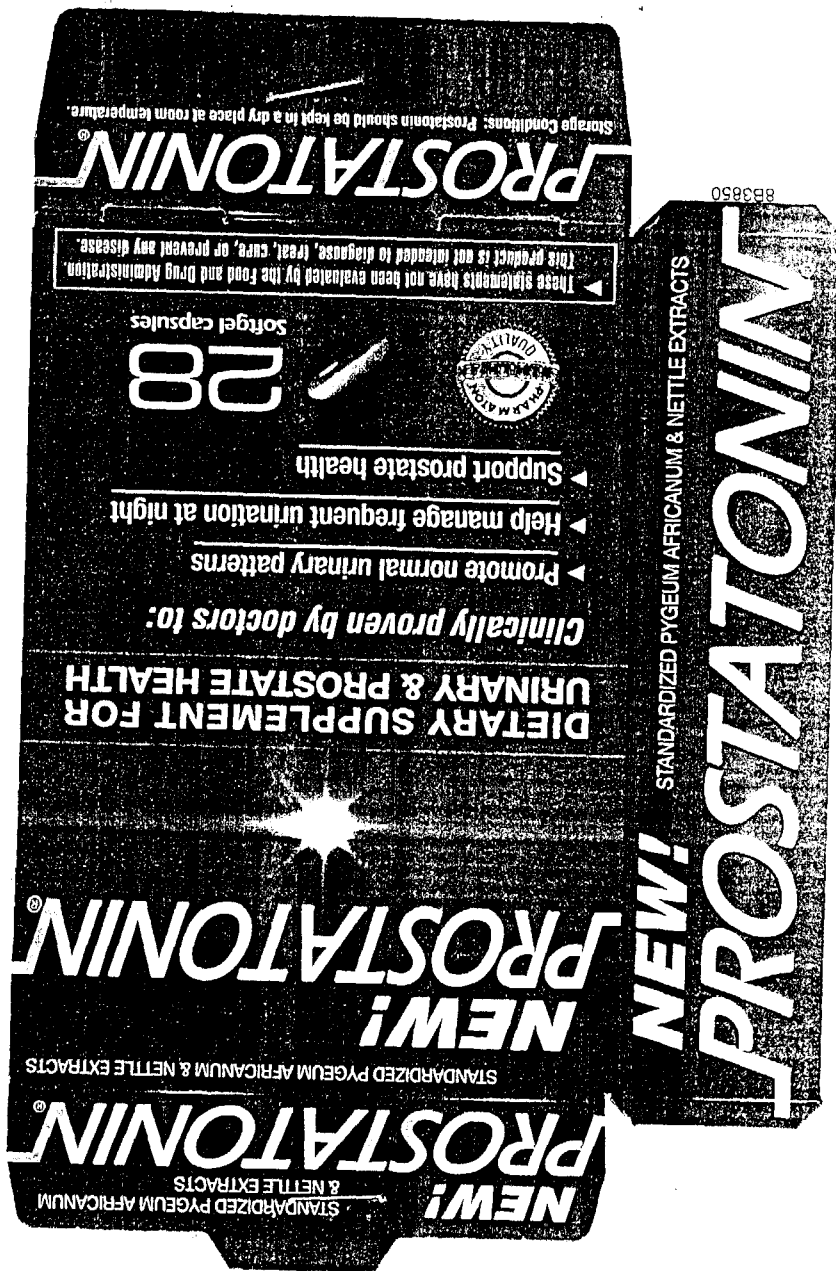
Sincerely,

A handwritten signature in black ink, appearing to read "Robert P. Carraher", written over a large, loopy flourish.

Robert P. Carraher

Enclosure

Original plus two copies enclosed

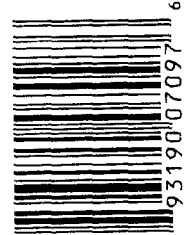


PROSTATONIN is a registered trademark of Pharmaton SA.
 Imported and distributed by: **PHARMATON**
 NATURAL HEALTH PRODUCTS
 Ridgefield, CT 06877

Product of Switzerland

Safety sealed for your protection.
 Do not use if individual blister seals are broken.

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SUPPLEMENT FACTS:	
Serving Size 1 capsule	
Amount Per Capsule	
Standardized Pygeum africanum extract PY 102 (bark)	25mg
Standardized Urtica dioica extract UR 102 (root)	300mg
Daily Value not established	

Other Ingredients: Rape oil, Gelatin, Triglycerides, Glycerol, Sorbitol, Soya lecithin, Synthetic iron oxides, Titanium dioxide.

Contains no sugar, caffeine, or artificial stimulants.

Satisfaction or your money back.

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Not all prostate supplements are the same. Unlike single-herb prostate supplements, PROSTATONIN combines two clinically proven herbal extracts: Nettle root (*Urtica dioica*, UR102) and African Plum tree bark (*Pygeum africanum*, PY102). As men age, their testosterone hormone levels can start to decrease which may affect prostate function. PROSTATONIN helps men maintain a normal hormonal balance which promotes normal urinary flow and prostate health.

When taken as directed, PROSTATONIN's dual-herbal formula safely and effectively helps you better manage sleep disruptions due to frequent urination and the urgency experienced between bathroom visits.

Adult males should take one softgel capsule twice a day with water (in the morning and evening with meals). Like most herbal supplements, PROSTATONIN takes time to work; optimal effectiveness has been shown after 6 weeks with continuous uninterrupted use.

As with other vitamins and supplements, please keep this product out of the reach of children. In case of accidental overdose, seek advice of a professional immediately. If you are receiving medical treatment, and taking medication for a prostate problem, or experiencing symptoms of a prostate problem such as painful, frequent or difficult urination, consult your physician.



Questions about PROSTATONIN?
 Call toll-free 1-800-203-2916